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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/623,477

07/18/2003

Robert L. Fischer

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 05/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/623,477

Applicant(s)

FISCHER ET AL.

Examiner

Cynthia Collins

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1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 80-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 80-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1004_0206</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group III, claims 80-84, in the reply filed on February 7, 2006 is acknowledged. Claims 1-79 and 85-89 are cancelled. Claim 80 is currently amended. Claims 80-84 are pending and are examined.

Specification

The abstract of the disclosure is objected to because the abstract is not commensurate in scope with the elected invention. Correction is required. See MPEP § 608.01(b).

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

Claim 80 is objected to because of the following informalities: the claim contains a backslash “\” that appears to be inadvertent. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 80 and 82-83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated nucleic acid molecule comprising an ANT promoter sequence that is at least 80% identical to SEQ ID NO:3, including a sequence further comprising a heterologous polynucleotide operably linked to the ANT promoter sequence and including the sequence as shown in SEQ ID NO:3. The claims are also drawn to a method of using said sequences in plant cells.

The specification describes SEQ ID NO:3 as a 4228 nucleotide sequence 5'-upstream sequence of the ANT gene (pages 41-42). The specification does not describe other sequences that are variants of SEQ ID NO:3 and that have promoter function.

The Federal Circuit has recently clarified the application of the written description requirement to nucleotide sequences. The court stated that "A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

In the instant case Applicant has not described a representative number of species falling within the scope of the claimed genus which encompasses numerous undisclosed and uncharacterized variants of SEQ ID NO:3 that have at least 80% identity to SEQ ID NO:3 and that have promoter function, nor the structural features unique to the genus.

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Claims 80-84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to an isolated nucleic acid molecule comprising an ANT promoter sequence that is at least 80% identical to SEQ ID NO:3, including a sequence further comprising a heterologous polynucleotide operably linked to the ANT promoter sequence and including the sequence as shown in SEQ ID NO:3. The claims are also drawn to a method of using said sequences in plant cells.

The specification discloses SEQ ID NO:3 as a 4228 nucleotide sequence 5'-upstream sequence of the ANT gene (pages 41-42). The specification at page 26 also proposes that promoter sequences from the ANT gene (SEQ ID NO:3) can be used to direct expression of the ANT coding sequence or heterologous sequences in desired tissues, and discloses that ANT is expressed in meristematic cells throughout the plant. The specification does not disclose the use of SEQ ID NO:3 as a promoter, or the use of other sequences that are variants of SEQ ID NO:3 as promoters.

The claimed invention is not enabled because it is unpredictable whether SEQ ID NO:3 or variants that are at least 80% identical to SEQ ID NO:3 would function as a promoter in plant cells or in the meristematic cells of a plant, because promoter function in plant cells or in the meristematic cells of a plant requires the presence of specific nucleotides and nucleotide sequence motifs in the polynucleotide, which nucleotides and motifs may not be present in fragments or sequence variants of SEQ ID NO:3.

See, for example, Kim Y et al. (A 20 nucleotide upstream element is essential for the nopaline synthase (*nos*) promoter activity. *Plant Mol Biol.* 1994 Jan;24(1):105-17), who teach that various point mutations in the *nos* promoter can alter the level of promoter activity in tobacco. Mutation of one or more key nucleotides in either of two hexamer motifs or in the octamer spacer region between them significantly altered the level of *nos* promoter activity (Table 2, page 109). A single point mutation in the sixth nucleotide of the hexamer motif resulted in a four to ten fold decrease in promoter activity, whereas a double point mutation in the fourth and fifth nucleotide of the hexamer motif resulted in a two-fold increase in promoter activity. Two independent triple point mutations in the third, fourth and fifth, and sixth, seventh and eighth nucleotides of the octamer spacer region eliminated detectable promoter activity.

See, for example, Kosugi S. et al. (Two of three promoter elements identified in a rice gene for proliferating cell nuclear antigen are essential for meristematic tissue-specific expression. *Plant J.* 1995 Jun;7(6):877-86), who identified three cis-acting elements in a rice proliferating cell nuclear antigen (PCNA) promoter truncated to position -263, that was previously shown to confer meristematic tissue-specific expression in transgenic plants, said cis-acting elements designated site I (-201 to -194, CCAGGTGG), site IIa (-197 to -188, TGGGCCCGT) and site IIb (-178 to -169, TGGTCCCAC). Kosugi S. et al. teach that functional analysis of the expression of PCNA-GUS gene fusions in transgenic tobacco plants revealed that a mutation in site I in the full-length 2.0 kb promoter had no significant effect on the activity, whereas the mutation in site I in the truncated -263 promoter, which had 14% of the activity of the full-length promoter, caused a considerable decrease in the activity, suggesting that site I

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contributes in part to transcriptional activation. Kosugi S. et al. also teach that simultaneous disruption of sites IIa and IIb in the full-length promoter caused about 80-85% loss of promoter activity, whereas separate disruption of site IIa or site IIb resulted in no marked change on the activity. Kosugi S. et al. additionally teach that these observations suggest that site IIa and site IIb play an important role in the meristematic tissue-specific expression of the rice PCNA gene, presumably by mediating putative enhancer activities dependent on the far-upstream region. (abstract; page 882 Figure 6)

In the instant case Applicant has not provided guidance with respect to the identity and location of key nucleotides and regulatory regions in SEQ ID NO:3 or variants that are at least 80% identical to SEQ ID NO:3 that are required for promoter function in plant cells or in the meristematic cells of a plant. Absent such guidance it would require undue experimentation for one skilled in the art to use SEQ ID NO:3 or variants that are at least 80% identical to SEQ ID NO:3, as one skilled in the art would have to test each sequence for promoter function and/or modify each sequence in order to determine under which conditions, if any, each sequence will function as a promoter in plant cells or in the meristematic cells of a plant. Such a trial and error approach to practicing the claimed invention would constitute undue experimentation.

Remarks

No claim is allowed.

Claims 80-84 are deemed free of the prior art of record due to the failure of the prior art to teach or suggest an isolated nucleic acid molecule comprising SEQ ID NO:3 or variants that are at least 80% identical to SEQ ID NO:3.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Primary Examiner
Art Unit 1638

CC


4/18/06